IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

ALTON BASS	§	
	§	
VS.	§	CIVIL ACTION NO. 4:09-CV-632-Y
	§	
STRYKER CORPORATION, et al.	§	

ORDER GRANTING MOTION TO DISMISS

Before the Court is Defendants' Rule 12(b)(6) Motion to Dismiss (doc. #14). After review, the Court will grant Defendants' motion.

I. Background

As set out in the original complaint, plaintiff Alton Bass underwent hip replacement surgery in August 2007. During that surgery, Bass's left hip was replaced with a Trident hip prosthesis ("Trident System") allegedly designed, manufactured, and marketed by defendant Stryker Corporation ("Stryker"). The Trident System is alleged to consist of four components: a Trident PSL Acetabular Shell, an Accolade TMZ Plus Hip Stem, a V40 Alumina Femoral Head, and a Trident 0 Alumina Insert. Bass alleges that despite following his surgeon's instructions, he began experiencing pain in his hip before the end of 2007, and the pain increased incrementally over the course of 2008 and 2009. Ultimately, in 2009 Bass underwent a revision of the hip-replacement surgery. During the revision surgery, it was discovered that the Trident PSL Acetabular Shell ("the Shell"), which replaces and functions as the socket portion of the hip joint, had failed to fuse with Bass's hip bone. Bass insists that the failure of the Shell to function properly caused him pain and discomfort, and he seeks to recover under a number of theories, including products liability, negligence, and breach of warranty, as well as under the Texas Deceptive Trade Practices Act.

Defendants have filed a Motion to Dismiss (doc # 14), arguing that each of Plaintiff's claims is preempted by the United States Supreme Court's interpretation of the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetics Act ("FDCA") in *Riegel v. Medtronic, Inc.*, 552 U.S. 312

(2008). According to Defendants, the Shell received pre-market approval from the Food and Drug Administration ("FDA") as a component of the Trident System and, therefore, a state may not subject it to requirements that are different from or in addition to those already imposed by federal law. In response, Plaintiff asserts that his claims are not preempted because they do not invoke "different" or "additional" requirements, but merely those that are "parallel" to the federal requirements.

In *Riegel*, the Supreme Court indicated that § 360k of the MDA does not bar a state from providing relief for persons asserting such parallel claims because they do not limit or add to the federal requirements. *Riegel*, 552 U.S. at 329. Defendants retort, however, that while parallel claims are permissible under § 360k(a), they are nevertheless preempted by § 337(a)'s language that only the United States is to enforce the FDCA, which implies that there is no private right of action. The Court granted leave for additional briefing on this issue--that is, whether § 337(a)'s language calls for preemption of claims that are otherwise permissible as parallel claims under *Riegel*'s interpretation of § 360k(a).

II. Discussion

A. Standard for Dismissal Under Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure 12(b)(6) authorizes the dismissal of a complaint that fails "to state a claim upon which relief can be granted." This rule must be interpreted in conjunction with Rule 8(a), which sets forth the requirements for pleading a claim for relief in federal court. Rule 8(a) calls for "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a); *see also Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 508 (2002) (holding Rule 8(a)'s simplified pleading standard applies to most civil actions). As a result, "[a] motion to dismiss for failure to state a claim is viewed with disfavor and is rarely granted." *Kaiser Aluminum & Chem. Sales v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1050 (5th Cir. 1982) (quoting Wright & Miller, Federal Practice and Procedure § 1357 (1969)).

The plaintiff must, however, plead specific facts, not mere conclusory allegations, to avoid dismissal. *Guidry v. Bank of LaPlace*, 954 F.2d 278, 281 (5th Cir. 1992). Indeed, the plaintiff must plead "enough facts to state a claim to relief that is plausible on its face," and his "factual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007).

A court must accept as true all well-pleaded, non-conclusory allegations in the complaint and liberally construe the complaint in favor of the plaintiff. *Kaiser Aluminum*, 677 F.2d at 1050. And although a court must generally limit its inquiry to the facts stated in the complaint, a court may also consider documents attached to or incorporated in the complaint, as well as matters of public record. *See* FED. R. CIV. P. 10(c); *Norris v. Hearst Trust*, 500 F.3d 454, 461 n.9 (5th Cir. 2007); *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir. 2000); *Lovelace v. Software Spectrum, Inc*., 78 F.3d 1015, 1017-18 (5th Cir. 1996).

B. Analysis

Defendants argue that Bass's state-law claims are preempted by the Medical Device Amendments ("MDA") of 1976 to the Food, Drug and Cosmetics Act ("FDCA"). Bass offers two responses. First, Bass argues that the MDA preempts only claims against devices that received "premarket approval" from the Food and Drug Administration ("FDA"). Bass insists that the Shell, as a mere component of the Trident System, did not receive premarket approval. Specifically, Bass contends that the Shell was approved prior to the overall Trident System under the less-rigorous process imposed by § 510(k) of the MDA. Second, Bass argues that his claims are not preempted by the MDA because they are "parallel" to relevant federal requirements.

1. Scope of Premarket Approval

The regulatory scheme established by the MDA created "various levels of oversight for medical devices, depending on the risk they present." *Riegel*, 552 U.S. at 317. Class III devices receive the most federal oversight. *See id.* A small percentage of Class III devices go through premarket approval, which includes a detailed multivolume application and a rigorous review process by the FDA, averaging 1,200 hours per application. *See id.* at 317-18. The FDA grants premarket approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (quoting 21 U.S.C. § 360e(d)). The vast majority of new Class III devices that are approved receive approval under § 510(k) of the MDA. *See id.* at 317. Class III devices already on the market before the MDA went into effect were grandfathered into the MDA's regulatory scheme in that they were allowed to remain on the market pending the FDA's promulgation of a regulation requiring premarket approval. *See id.* Section 510(k) authorizes the approval of new Class III devices that are "substantially equivalent" to premarket-approval exempt devices. *Id.*

Under the MDA, "[e]xcept as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

> "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> "(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

21 U.S.C. § 360k(a). A state-law tort claim to recover for injuries allegedly caused by a medical device governed by the MDA is preempted if: (1) the federal government has established a "requirement" applicable to the device within the meaning of § 360k(a); and (2) the state law invoked by the plaintiff imposes a requirement that is "different from, or in addition to" the federal requirement and relates to safety and effectiveness. *Riegel*, 552 U.S. at 321-22.

The first part of this test is always satisfied when a premarket-approved device is at issue. *See id.* at 322-23; *see also Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 526 (S.D. Tex. 2009) ("The Supreme Court found that all PMA-approved devices met the first prong of preemption under § 360k(a) because the FDA imposed device-specific requirements on them."). "Premarket approval . . . imposes 'requirements' under the MDA [and] premarket approval is specific to individual devices." *Riegel*, 552 U.S. at 322-23. Premarket approval "*is* federal safety review." *Id.* at 323 (emphasis in original).

Bass insists that the Shell is a separate medical device that received approval under the 510(k) process, rather than premarket approval. Both Bass and Defendants have provided to the Court a number of FDA documents relevant to the issue of whether the Trident System, including the Shell, received premarket approval. The documents submitted by Defendants persuade the Court that the FDA considered the Shell a component of the overall system and that the overall system received premarket approval. But Bass's point is that the Shell, as a medical device in its own right, was not tested and reviewed under the rigorous premarket-approval process described in *Riegel*. Instead, as a previously-approved device, it was merely incorporated into, and authorized for use in, the premarket-approved Trident System. Thus, Bass contends, the logic of *Riegel*'s discussion of preemption under the MDA does not apply.

Indeed, the summary of safety-and-effectiveness data issued in conjunction with the approval of the Trident System acknowledges the prior approval of the Shell, stating that the "ceramic-on-ceramic acetabular bearing couple," which consists of the alumina femoral head and alumina femoral inserts, is to be used with "the commercially available" Trident Acetabular Shell. Supplements to the premarket approval further support the position that the focus of the premarket approval was on the bearing couple, as the supplements allow for use of the system with other shells beyond the "shells previously approved for use" with the system's other components. (Def.'s Ex. C, Suppl. S004.) Most persuasive is Bass's inclusion in his appendix of the 510(k) approvals for the Trident Shells. In fact, the summary of safety-and-effectiveness data issued in conjunction with the approval of the predecessor to the Trident Acetabular

Shell states that the Shell "is compatible with any appropriately selected Osteonics hip stem/femoral head combination." These documents demonstrate that the Shell received prior approval under the 510(k) procedure as a medical device independently of the Trident System, and suggest that the FDA contemplated the Shell's use as a component in hip-replacement systems without further review of the Shell, just as Bass argues is the case here. That is, Bass argues that the fact that the FDA authorized the use of the Shell, which had previously been approved under § 510(k), as part of a system that received premarket approval is not equivalent to the Shell's itself being reviewed for and ultimately receiving premarket approval.

Defendants respond that district courts presented with the issue have almost unanimously concluded that claims against the Trident System are preempted by the MDA. *See, e.g.*, *Funk*, 673 F. Supp. 2d at 531 & n.4 (noting that in "nearly all of the prior district court cases addressing preemption of claims involving the Trident, both the plaintiffs and the defendants agreed it was a Class III device approved through the PMA process") (citing *Delaney v. Stryker Orthopedics*, No. 08-03210, 2009 U.S. Dist. LEXIS 16865 (D.N.J. Mar. 5, 2009)). And more specifically, Defendants argue that three courts have rejected the very argument made by Bass--that the preemption issue should be evaluated with regard to the Shell individually rather than the system as a whole. *See Lewkut v. Stryker Corp.*, No. 09-3695, 2010 U.S. Dist. LEXIS 38345, *10-*17 (S.D. Tex. Apr. 16, 2010); *Hayes v. Howmedica Osteonics Corp.*, No. 08-6104, at 45-63 (D.N.J. Dec. 15. 2009) (Def.'s Ex. D); *Delaney v. Stryker Orthopaedics*, No. 08-03210 (DMC), 2009 WL 564243, at *4 (D.N.J. Mar. 5, 2009). One of those courts discussed the relevant FDA records in considerable detail in reaching its conclusion. *See Lewkut*, 2010 U.S. Dist. LEXIS 38345, at *10-*17 ("[T]hat the acetabular shell was previously approved through only the § 510(k) process, and was commercially available when the Trident System was approved, does not change the fact that it was later subject to the more rigorous scrutiny of the PMA process as a component of the Trident System."). Specifically, the *Lewkut* court considered the Trident System's PMA approval letter, its Draft

Package Insert, and the FDA's Summary of Safety and Effectiveness Data. *Id.* at *10-*14. The court noted that many of the supplements given pre-market approval by the FDA after the Trident System's initial approval referred to the Shell as if it had been approved through the PMA process. *See id.* at *12.

Accordingly, Defendants have, by highlighting the position of the district courts that have addressed this specific issue, established that the Shell, as a component of the Trident System, was subject to the rigorous premarket-approval review on which the Supreme Court's analysis in *Riegel* was based, causing claims based on the Shell to be preempted under § 360k(a).

2. Parallel Claims

Bass also argues that, even assuming the Shell was granted premarket approval as part of the Trident System, dismissal is not appropriate because his claims are "parallel" to federal requirements. "State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. Thus, § 360k(a) does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 329.

"To properly allege parallel claims, the complaint must set forth facts showing 'action or inaction in [defendants'] efforts to take part in the PMA process or implement its results[.]'" *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Col. 2008) (quoting *Heisner ex rel. Heisner v. Genzyme Corp.*, 2008 U.S. Dist. LEXIS 60569, 2008 WL 2940811 at *5 (N.D. Ill. July 25, 2008)). In his complaint, Bass alleges that if the Trident System including the Shell received premarket approval, then "manufacturing deficiencies" and "material deviations" in the Shell caused his injuries. These unelaborated allegations do not provide enough facts to support a cause of action, and Bass's complaint makes no attempt to relate the alleged deficiencies and deviations to the premarket-approval process or Defendants' implementation of the approval. The complaint does not allege a failure to comply with any particular regulation nor how

that failure caused Bass's injuries. *Cf. id.* at 1302; *also cf. In re Medtronic Inc.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) (collecting cases and discussing factual sufficiency of manufacturing-defect claims based on violation of FDA regulations). Neither Bass's reference to the voluntary recall of certain shells by Defendants in 2008, nor to a warning letter issued by the FDA in March 2007 aides his effort to plead parallel claims. *See Parker*, 584 F. Supp. 2d at 1302; *see also In re Medtronic Inc.*, 592 F. Supp. 2d at 1155-56. Bass has, therefore, failed to plead parallel claims within the meaning of *Riegel*. *See Parker*, 584 F. Supp. 2d at 1302.

Moreover, even if Plaintiff's state-law claims are premised on Defendants' alleged failures to comply with federal requirements, those claims are nevertheless preempted because the FDCA and FDA regulations do not provide a private cause of action. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). It is on this point that the Court allowed additional briefing (doc. #34). Section 337(a) has been held to impliedly preempt private claims based on its language that "all proceedings for the enforcement or to restrain violations of the FDCA 'shall be by and in the name of the United States.'" *In re Medtronic, Inc.*, 592 F. Supp. 2d 1147 (D. Minn. 2009) (discussing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)). Thus, although the Supreme Court in "*Riegel* expressly recognized that 'parallel' claims--that is, claims 'premised on a violation of FDA regulations'--are not preempted [under § 360k(a)]," a plaintiff's characterizing his claims as parallel would be no response to a preemption argument under § 337(a). *See id.* 1160-61 & n.17.

Generally, therefore, a plaintiff cannot get around the absence of a federal private right of action by invoking state law. The *Medtronic* court, however, recognized two potential exceptions whereby a plaintiff could use parallel claims to avoid both forms of preemption. *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1161 n.17. Neither of these exceptions will work for Plaintiff. Under the first exception, according to the *Medtronic* court, a properly pleaded claim alleging a failure to adhere to PMA specifications could avoid preemption completely. *Id.* The court relied upon *Rollins v. St. Jude Medical, Daig Division, Inc.*,

583 F. Supp. 2d 790 (W.D. La. 2008), as support for this proposition. *Rollins*, however, dealt only with 360k(a) preemption--not that of 337(a). *See Rollins*, 583 F. Supp. 2d 790. Moreover, the persuasiveness of the reasoning behind this exception is diminished considering that, under *Buckman*, a claim that is "parallel"--and thus not preempted by § 360k(a)--is nevertheless preempted by § 337(a)'s language giving the United States the exclusive right to enforce the FDCA. *Buckman*, 531 U.S. at 349 n.4. Yet, even to the extent that this exception is legitimate, it affords Plaintiff no relief. Plaintiff has not specifically alleged how Defendants have failed to meet PMA specifications or that such a failure has even occurred. By contrast, the plaintiff *in Rollins* had amended his claim to include specific allegations that the manufacturer failed to meet PMA specifications. *Rollins*, 583 F. Supp. 2d at 800-01.

Under the second exception of *In re Medtronic*, a state statute may itself create a cause of action for violations of the FDCA. *In re Medtronic, Inc.*, 593 F. Supp. 2d at 1161 n.17. Here, however, even after additional briefing, Plaintiff has not cited any such statute. The only state statute that Plaintiff has mentioned is the Texas Deceptive Trade Practices Act, which does not provide a private cause of action for FDCA violations. Consequently, sections 337(a) and 360k(a) work in combination to preempt Plaintiff's claims.

III. Conclusion

In light of the foregoing, the Court concludes that Bass has failed to point to facts in the public record sufficient to make it plausible that his causes of action are not preempted by the MDA. The Shell, as a component of the Trident System, received approval through the PMA process. As a result, § 360k(a) preempts Plaintiff's claims against it. Even assuming that Plaintiff's claims are parallel claims, and therefore not preempted by § 360k(a), they are nevertheless preempted by § 337(a) because there is no private right of action under the FDCA. Any potential exceptions to preemption are not applicable here

as Plaintiff has not pleaded any failure of Defendants to meet FDCA specifications nor has he pointed to any state law granting a private right of action for violations of the FDCA.

Accordingly, Defendants' motion to dismiss is GRANTED.

SIGNED August 31, 2010.

Terry R. Means

TERRY R. MEANS
UNITED STATES DISTRICT JUDGE